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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,146

07/18/2006

John Francis Hoke

PB60428

9414

20462

7590

02/18/2009

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EXAMINER

WESTERBERG, NISSA M

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

02/18/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No. 10/567,146	Applicant(s) HOKE ET AL.	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22 - 26, 30 - 40, 42 - 44 is/are pending in the application.
- 4a) Of the above claim(s) 43 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22 - 26, 30 - 40, 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/6/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of the required presence of a third composition which is an enteric coating, having one or more openings extending substantially completely through the third composition and the treatment of diabetes mellitus in the reply filed on December 12, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant has argued that as Applicant has elected to prosecute the claims directed to the dosage forms, the method of treatment claims should be rejoined in this application. The Examiner has only required a species election regarding the dosage form and the condition being treated and therefore the method of treatment claims 42 – 44 were never separated from each other and therefore no rejoinder of the claims is required.

The requirement is still deemed proper and is therefore made FINAL.

Specification

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2. The disclosure is objected to because of the following informalities: while a drawing is present in the Application, the Specification as filed does not contain a section "Brief Description of the Drawings".

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 22 – 25, 35 – 40 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 3, 7 and 10 – 13 of copending Application No. 10/502376 in view of Glinecke et al. (WO 0/28900). The claims of the instant application recite an oral dosage form comprising the weak base 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione (rosiglitazone) in both a first and second composition, the two compositions having different release rates and a third composition which is non-permeable enteric coating that comprises one or more openings extending substantially completely through the third composition. A process of preparing the dosage form and a method of treating a disorder which can be treated by administration of rosiglitazone such as diabetes mellitus are claimed.

The claims of '376 recite an oral dosage form comprising an erodable core that comprises a weak base such as rosiglitazone (claim 11) and an erodable coating which comprises one or more opening extending substantially through the coating. The erodable coating can be an enteric coating (claims 2 and 3) and the core can be multi-layered (claim 7). A process of preparing the dosage form and a method of treating a disorder which can be treated by administration of a weak base are claimed.

'376 does not recite that the different layers of the dosage form having different release rates.

Glinecke et al. disclose modified release compositions useful for the treatment of diabetes mellitus that contain insulin sensitizers such as rosiglitazone (compound (I); p 1, ln 3 – 11, 29 – 34). The modified release may be a pulsed release (p 2, ln 9) such as that provided by a combination of non-modified (immediate) and delayed (modified) release of the active agent (p 3, ln 16 – 29). Delayed release can be provided by enteric coated tablets with more than one layer, wherein the active agent is present in one or more discrete layers (compositions) within the compressed tablet form and arranged as required to provide modified or non-modified release of the active agent (p 2, ln 18 – 21).

It would have been obvious to one of ordinary skill in the art to prepare a multi-layered, erodable core tablet with an erodable enteric coating as recited by claims of '376 and to have the different layers (compositions) of the core have a different release profiles for the active ingredient. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Glinecke et al. teaches the desirability of having an immediate and modified release component for oral dosage forms or rosiglitazone, an active ingredient claimed by '376 as suitable for inclusion in the erodable dosage form.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112 – 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 30 – 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. Each of these claims requires an arrangement of the first and second compositions that provides particular release characteristics when the dosage form is administered (e.g., the release of substantially all of the drug compound in the first composition in the stomach). Applicant described three different bilayer tablet dosage forms in the specification but does not provide any information about how the first and second compositions are arranged in the tablet core, such as if the immediate release composition surrounds the modified release composition, or if the tablet is divided in half so that each end or side of the tablet has a different composition or information about the relation of the openings in the non-permeable, enteric coating to the different compositions. A dosage form with both an modified and immediate release composition is administered and is said to be have pharmacokinetic parameters which are independent of food during use, but it is not clear which formulation from the examples

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was administered. Information regarding the location of drug release (stomach and/or small intestine) from the first and second compositions is not provided. Given the lack of information regarding the arrangements of the first and second compositions which provide the claimed features of the oral dosage form, Applicant has not provided adequate information in the specification to convey to one skilled in the art the structural arrangements which are required to provide the claimed features.

Claim Rejections - 35 USC § 112 2nd Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 22 – 26, 30 – 40 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The first and second compositions have differing release rates on administration (line 6 – 7 of claim 22). It is unclear whether only one of these release rates must be substantially independent of pH or if the release rates from the first and second compositions must be substantially independent of pH in order for the limitations in lines 6 – 8 of claim 22 to be met. It also unclear what is meant by “non-permeable” in line 10 of claim 22 and if the enteric coating layer is not permeable to anything and/or if the layer is only impermeable to some agents, such as the active agent and/or the environmental fluid.

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9. Claims 22 – 26, 30 – 40 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "substantially independent of pH" in claims 22 and 39 is a relative term which renders the claim indefinite. The term "substantially independent of pH" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, it is unclear how much of a dependence on pH the release rate can show while being "substantially independent of pH" or if a rate that is completely independent of pH is required for this limitation to be met. The phrase "one or more openings extending substantially completely through the third composition" in claims 22 and 40 is a relative phrase which renders the claim indefinite. The term "substantially completely through" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear if the openings must extend all the way through the third composition or if some, non-defined amount of the third composition can remain at one end of the opening.

Similar reasoning applies to the phrases "substantially greater than the release rate of the drug compound from the second composition" in claim 23, "arranged to release substantially all of the drug compound" in claims 30 and 31 and "maintained substantially independent of food during use" in claims 32– 34. In each of these cases,

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the lack of definition of “substantial” either in the claims or specification renders the claim indefinite.

10. Claims 35 – 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 35 requires that “release of the drug compound from the erodable core occurs substantially through the one or more openings and through erosion of said erodable coating under pre-determined pH conditions”. The beginning of the phrase implies that almost all, if not all, of the drug release occurs through the one or more openings but the remainder of the phrase indicates that release also must occur through another mechanism, namely erosion of the erodable coating. Therefore, what is meant by the relative term of release being substantially through the one or more openings cannot be determined. Also, what is meant by “pre-determined pH conditions” is not definite as if those pH conditions can be any condition, as long as they are determined before hand, or if specific pH values and/or times are required, for this limitation of the claim to be met.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 22 – 26, 30 – 40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staniforth (US 5,004,614) in view of Glinecke et al. (WO 00/28990).

Staniforth discloses a controlled release delivery device comprising a core with an active agent and an outer coating covering the core which includes an orifice which connects that use environment to the core, allowing for release of the active agent (col

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3, ln 27 – 32). The coating is adapted so that it is substantially impermeable to the release of the active agent during a pre-determined dispensing period (col 3, ln 34 – 35). The active agent may comprise a wide variety of chemical compounds, which may possess a wide range of solubilities (col 3, ln 50 – 52) including hypoglycemics (col 6, ln 21). Relatively thick coatings of enteric materials can be used to provide the substantially impermeable to the environmental fluid coating (col 6, ln 60 – 67, 23 – 26). The dosage form can be in the form of tablets (col 3, ln 56 – 58) and the dosage form can be multi-layered in order to provide a loading dose or for releasing two or more active agents (col 10, ln 11 – 15). It is preferred that the openings extend through the entire impermeable layer so that there is immediate exposure of the core of the device (col 7, ln 57 – 60). This allows for rate of release of the agent through the orifice to be constant as the drug and excipients are continually eroded but the exposed surface moves further away from the opening (col 9, ln 3 – 12). The tablets cores formulated comprising active ingredient and lactose as a pharmaceutically acceptable carrier are prepared and then coated with the coating formulation (col 10, ln 39 – 54). Openings extending completely through the coating but not extending into the tablet core are then formed, communicating from the environment of use to said core (col 11, ln 21 – 25).

Staniforth does not exemplify rosiglitazone as a suitable active agent or the inclusion of compositions with differing release rates with the non-permeable enteric coating composition.

Glinecke et al. disclose modified release compositions useful for the treatment of diabetes mellitus that contain insulin sensitizers such as rosiglitazone (compound (I); p

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1, ln 3 – 11, 29 – 34). The modified release may be a pulsed release (p 2, ln 9) such as that provided by a combination of non-modified (immediate) and delayed (modified) release of the active agent (p 3, ln 16 – 29). Delayed release can be provided by enteric coated tablets with more than one layer, wherein the active agent is present in one or more discrete layers (compositions) within the compressed tablet form and arranged as required to provide modified or non-modified release of the active agent (p 2, ln 18 – 21).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate a multi-layer tablet containing rosiglitazone with a modified and non-modified release profile into the controlled release device comprising a core and coating with an opening as taught by Staniforth. The person of ordinary skill in the art would have been motivated to make those modifications because the dosage form of Staniforth allows for the desirable zero-order release of the active agent wherein the release rate is independent of the concentration of the active ingredient (col 10, ln 16 – 26) while providing the modified overall release profile of rosiglitazone as taught by Glinecke et al. The optimization of drug release rates is results effective parameter. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. The person of ordinary skill in the art reasonably would have expected success because both Staniforth and Glinecke et al. deal with tablet pharmaceutical dosage form and ways in which the release of the active ingredient from the dosage form can be controlled.

The prior art teaches a non-permeable enteric coated dosage form with openings that extend completely through the coating to the tablet core inside, wherein the tablet core contains an immediate and modified release composition as the first and second compositions respectively. The claims of the instant application recite a non-permeable enteric coated dosage form with openings that extend completely through the coating to the tablet core inside wherein the tablet core contains an immediate and modified release composition as the first and second compositions respectively. Therefore, the first composition will release all of the drug compound it contains in the stomach and the second composition will release all of the drug it contains in the small intestine as both the prior art and the claims recite a non-permeable enteric coated dosage form with openings that extend completely through the coating to the tablet core inside, wherein the tablet core contains an immediate and modified release composition as the first and second compositions respectively.

Similarly, because the structure recited by the prior art and the claims are the same, the mean maximum plasma level concentration level of the drug and the mean area under the plasma concentration versus time curve over the dosing interval at steady state will be maintained substantially independent of food during use and the mechanism of release of the drug will be the same. Thus, the release of the drug from the erodable core will occur substantially through the one or more openings and through erosion of said erodable coating.

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15. Claims 22 – 26, 30 – 40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martini et al. (WO 03/068195) in view of Glinecke et al. (WO 00/28990).

Martini et al. discloses an oral dosage form comprising an erodable core which contains a pharmaceutically acceptable weak base, the core having a coating with one or more openings leading to the core, wherein the coating is erodable under predetermined pH conditions (p 2, ln 25 – 29). Rosiglitazone is exemplified as a weak base suitable for use in the dosage form (compound A, p 3, ln 25 – 31) which is suitable for the treatment of diabetes mellitus (p 3, ln 35). While the erosion of the coating is pH-dependent, the core may release the active substance by eroding in a non-pH dependent manner (p 6, ln 27 – 29). The core can contain more than one layer (p 8, ln 35 – 36). So that the openings in the coatings retain their integrity and control the release rate, it is desirable that the pH dependent erosion of the coating does not substantially erode except in the intestine, a material which reads on an enteric coating layer (p 7, ln 1 – 3). Preferably the dissolution rates are arranged by routine adjustment of the erodable coating and dimension of the openings so that the release rate is substantially uniform in the different pH environments experienced by the dosage form upon administration or, in other words, that the rate of release of the drug compound from the dosage form is substantially independent of pH (p 12, ln 21 – 25). The dosage form can be prepared by formulating an erodable tablet core, coating the tablet core with a coating formulation and creating one or more openings in the coating, which

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extend substantially completely through the coating but do not penetrate the core and communicating from the environment of use to said core (p 8, ln 1 - 8).

Martini et al. does not disclose inclusion of an erodable tablet core with two compositions having differing release rates of rosiglitazone.

Glinecke et al. discloses modified release compositions useful for the treatment of diabetes mellitus that contain insulin sensitizers such as rosiglitazone (compound (I); p 1, ln 3 – 11, 29 – 34). The modified release may be a pulsed release (p 2, ln 9) such as that provided by a combination of non-modified (immediate) and delayed (modified) release of the active agent (p 3, ln 16 – 29). Delayed release can be provided by enteric coated tablets with more than one layer, wherein the active agent is present in one or more discrete layers (compositions) within the compressed tablet form and arranged as required to provide modified or non-modified release of the active agent (p 2, ln 18 – 21).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate the immediate and modified release tablet of Glinecke et al. into the erodable tablet dosage form of Martini et al. The person of ordinary skill in the art would have been motivated to make those modifications, and reasonably would have expected success because both references relate to oral dosage forms for the anti-diabetic medications such as rosiglitazone and that the combination of different release profiles from the core based on the use of different composition in the core and further controlling the dissolution and release of the active

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agent from the core by the addition of a non-permeable enteric coating with openings extending through the coating.

The prior art teaches a non-permeable enteric coated dosage form with openings that extend completely through the coating to the tablet core inside, wherein the tablet core contains an immediate and modified release composition as the first and second compositions respectively. The claims of the instant application recite a non-permeable enteric coated dosage form with openings that extend completely through the coating to the tablet core inside wherein the tablet core contains an immediate and modified release composition as the first and second compositions respectively. Therefore, the first composition will release all of the drug compound it contains in the stomach and the second composition will release all of the drug it contains in the small intestine as both the prior art and the claims recite a non-permeable enteric coated dosage form with openings that extend completely through the coating to the tablet core inside, wherein the tablet core contains an immediate and modified release composition as the first and second compositions respectively.

Similarly, because the structure recited by the prior art and the claims are the same, the mean maximum plasma level concentration level of the drug and the mean area under the plasma concentration versus time curve over the dosing interval at steady state will be maintained substantially independent of food during use and the mechanism of release of the drug will be the same. Thus, the release of the drug from the erodable core will occur substantially through the one or more openings and through erosion of said erodable coating.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW